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IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/314,889 05/19/99 YU

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EXAMINER

ULM, J
ART UNIT

PAPER NUMBER

1646
DATE MAILED:

11
02/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/314,889

Applicant(s)
Yu et al.

Examiner
John Ulm

Group Art Unit
1646



☒ Responsive to communication(s) filed on Dec 5, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 27-119 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 27-119 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

1) Claims 27 to 119 are pending in the instant application. Claim 22 has been canceled and claims 42, 56, 69, 80, 101 and 119 have been amended as requested by Applicant in Paper Number 10, filed 05 December of 2000.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 57, 62 to 70, 73 to 81 and 94 to 100 remain objected to as reciting an improper Markush Group because the amino acid sequences recited in the Markush groups of claims 57, 70 and 81 lack a common utility which is based upon a common structural feature disclosed as a basis for that common utility. Applicant is required to cancel the claims, or amend the claims to place them in proper form. In traversing this objection, Applicant has failed to identify a common utility which is based upon a common structural feature disclosed as a basis for that common utility. This is an objection to the form of the claims and has nothing to do with a restriction requirement. M.P.E.P. 803.02 has only been relied upon because it defines the proper content of a Markush Group.

5) Claims 27 to 119 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 4 of Paper Number 9. Applicant asserts that the proteins of the instant invention have specific and substantial utility because they induce apoptosis. Applicant has

Art Unit: 1646

failed to identify the practical benefit to be derived from the disclosure of a protein which induces apoptosis upon overexpression in a cell. Numerous receptor proteins induce either apoptosis (death domain-containing proteins) or cell proliferation (receptor tyrosine kinases) when ligand activated or overexpressed in a cell. There is no evidence that the particular receptor identified in the instant application is in any way associated with the plurality of diseases and disorders listed on lines 23 to 26 on page 5 of the instant specification. The fact that apoptosis may play a role in any one or more of those diseases or disorders does not support a conclusion that apoptosis caused by the activation of those particular proteins which are the subject of the instant invention has any role in any of those diseases or disorders.

Applicant has traversed this rejection of the premise that it is in conflict with Example 10 of the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS". That example involves the probability that a nucleic acid encoding a protein which is structurally related to a well known and commercially useful class of enzymes encodes an enzyme with similar activity. The proper analysis of the instant claims, which are drawn to an isolated nucleic acid encoding an orphan receptor, should be made in light of Example 12 of those guidelines, which explains why an isolated nucleic acid encoding an "orphan receptor" lacks utility in the absence of the disclosure of a specific role for either the nucleic acid or protein in a known disease or disorder or a physiological process which one would wish to manipulate for clinical effect.

Art Unit: 1646

6) Claims 27 to 119 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) Claims 43 to 56 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims expressly require the biological material recited therein to make the claimed invention. Applicant asserts that a Declaration for Deposited Biological Materials has been submitted but no such declaration is currently present in the instant application.

8) Claims 27 to 119 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Kitson et al. publication (NATURE 384:372-375, 28 Nov. 1996) for those reasons of record in section 8 of Paper Number 9. As stated therein, because of the rejection of these claims for lack of utility under the first paragraph of 35 U.S.C. § 112 above, the instant application does not receive benefit under 35 U.S.C. § 120 from any prior applications. Applicant's traversal of this rejection completely ignores 35 U.S.C. § 120, upon which it is based.

9) Applicant's arguments filed 05 December of 2000 have been fully considered but they are not persuasive for those reasons given above.

10) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1646


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800